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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,800	03/30/2005	David C Racnct	2863(203-3511)	5353
50855	7590	10/17/2007		
COVIDIEN 60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473			EXAMINER LOPEZ, MICHELLE	
			ART UNIT 3721	PAPER NUMBER
			MAIL DATE 10/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,800

Applicant(s)

RACENET, DAVID C

Examiner

Michelle Lopez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment filed on 1/29/07.

DOUBLE PATENTING REJECTION

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 34-36, 38, 45-48, and 51-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-32, 34, and 37-41 of copending Application No. 10/529799. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a tool assembly comprising an anvil and cartridge assembly, a clamp member, and a dynamic clamping member. While the claims of the present application and the claims of the copending application may have variations and differences in their scope and terminology, the variations and differences would have been obvious to one having ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 42-43 and 49-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-32, 34, and 37-41 of copending Application No. 10/529799 in view of Milliman 6,669,073. The claims of the copending application disclose the present invention substantially as claimed, but fail to disclose a knife blade formed on a central body portion of the dynamic clamping member. However, Milliman shows a tool assembly having a dynamic clamping member with a knife blade as claimed as shown in figs. 29, 45, 49, 51-52. It would have been obvious to one having ordinary skill in the art to have provided the present application with a knife blade as taught by Milliman in order to cut clamped tissue upon forward movement of the dynamic clamping member.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-27, 34-39, 42-43, and 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontayne 5,485,952 in view of Milliman 6,669,073.

Fontayne discloses a tool assembly comprising an anvil 18 and a cartridge assembly 16, the cartridge assembly having a plurality of fasteners and being movable in relation to the anvil between a spaced position and an approximated position, the cartridge assembly and the anvil defining a tissue gap in the approximated position, a clamp member 90 positioned adjacent a proximal end of the cartridge assembly and the anvil and being movable from a first position to a

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second position to maintain the proximal end of the cartridge assembly and the anvil in juxtaposed alignment, i.e. close together, and a dynamic clamping member at the proximal end of 280 movable positioned in relation to the anvil and the cartridge assembly as shown in figs.12-14, but fails to disclose wherein the dynamic clamping member being movable from a first position to a second position to define a tissue gap between the cartridge and the anvil adjacent the dynamic clamping member during ejection of fasteners from the cartridge.

However, Milliman shows a tool assembly comprising an anvil and cartridge assembly, and a dynamic clamping member being movable as broadly claimed as shown in figs. 49, 51-52. It would have been obvious to one having ordinary skill in the art to have provided Fontayne's tool assembly with a dynamic clamping member as taught by Milliman in order to press the anvil and cartridge assembly together so as to hold them firmly while the dynamic clamping member is moved forward along the tool assembly.

Fontayne also discloses a drive member 266 operably connected to the clamp member and the dynamic clamping member, the drive member being formed from a flexible cable and being movable to move the clamp member and the dynamic the dynamic clamping member between their first and second positions (claim 27); wherein the tool assembly is pivotally secured to a body portion 12 of a stapling device (claim 34); wherein the tool assembly is operably connected to a collar member 154 and the collar member is pivotally secured to the body portion of the stapling device (claim 35); wherein the tool assembly is rotatably mounted to the collar member as shown in Fig. 8(claim 36); wherein the dynamic clamping member is supported in the tool assembly (claim 37); wherein the clamp member is annular and is positioned about a proximal end of the anvil and of the cartridge assembly in its second position

(claim 39); a knife blade 265 formed on the dynamic clamping member (claims 42-43); wherein the first position of the dynamic clamping member is adjacent a proximal end of the tool assembly and the second position of the dynamic clamping member is adjacent a distal end of the tool assembly (claim 45); a sled 276 and at least one pusher 304, the sled being driven by the dynamic clamping member as shown in Fig. 4 (claim 46); and a plurality of staples and pushers as shown in Fig. 4 (claim 47); a knife blade 265 (claims 49-50); a sled 276 and at least one pusher 304 (claim 51); and a plurality of staples and pushers (claim 52).

Milliman also shows a surgical stapling apparatus comprising a tool assembly with an anvil assembly 20 and a cartridge assembly 18, and a dynamic clamping member having a first portion which engage the anvil assembly and a second flange portion which engage the cartridge assembly (claim 38); the lower flange portion of the dynamic clamping member has a rounded cross-section 287 along an axis traverse to a longitudinal axis of the cartridge assembly as shown in Figs. 12A-12B (claim 48); the upper and lower flange portions are substantially vertically aligned and a knife blade disposed on a central body portion between the upper and the lower flange portions as shown in Fig. 45 (claims 53-54).

Claims 28-33, 40-41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontayne 5,485,952 in view of Milliman 6,69,073, as applied to claim 26 as discussed above, and further in view of Bolanos (5,690,269).

The modified tool assembly of Fontayne discloses a flexible drive member as a center rod 155, but does not disclose wherein the drive member is a coaxial drive cable including an outer sheath and a center rod. Bolanos teaches the concept of a drive member having a coaxial drive cable with an outer sheath 200 and a center rod 70 for the purpose of properly articulating an

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endoscopic portion. It would have been obvious to one having ordinary skill in the art to have substituted Fontayne's drive member by a coaxial drive cable as taught by Bolanos to articulate the tool assembly.

Bolanos also teaches wherein the center rod 70 is movable and axially movable with respect to the outer sheath (claims 29-30).

With respect to claim 31, it is deemed that Bolanos' center rod 70 is rotatable in relation to the outer sheath as shown in Fig. 8.

With respect to claim 32, Bolanos also shows wherein the outer sheath 200 is operably connected to a clamp member as shown in Fig. 12.

With respect to claim 33, Bolanos also shows wherein the center rod 70 is operably connected to a dynamic clamping member 136.

With respect to claims 40-41, the modified invention of Fontayne does not specifically disclose wherein the center rod is formed from wound flexible cable and that the outer sheath is selected from the group consisting of steel mesh, plastic, nitinol, and Kevlar. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a wound flexible cable and an outer sheath as claimed, since it has been held to be within the general skill in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With respect to claim 44, Bolanos also shows a drive collar wherein the outer sheath 200 is fixedly attached to a drive collar as shown in Figs. 12-13 (claim 44).

Response to Arguments

Applicant's arguments with respect to claim 26 have been considered but are moot in view of the new ground(s) of rejection.

Applicant contends that the combination of Fontayne and Milliman fails to disclose or suggest the dynamic clamping member recited in claim 26. However, Examiner contends that Milliman shows a dynamic clamping member movable between a first and a second position to define a tissue gap between the anvil and the cartridge assembly while translating forward along the tool assembly as broadly claimed. Note that Milliman's dynamic clamping member clamps, i.e. press the anvil and cartridge assembly together so as to hold them firmly, while traveling along the tool assembly, and thereby maintaining a desired tissue gap between said anvil and cartridge assembly during ejection of the fasteners. Applicant also, contends wherein Milliman dynamic clamping member does not has a rounded cross-section along an axis transverse to a longitudinal axis of the cartridge assembly. However, Examiner asserts that Milliman does show said rounded cross-section as claimed as shown in figs. 12A-12B.

For the reasons above the grounds of rejection are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Lopez whose telephone number is 571-272-4464. The examiner can normally be reached on Monday - Thursday: 8:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ML/
Patent Examiner

A handwritten signature in black ink, appearing to read 'Rinaldi I. Rada', with a long horizontal flourish extending to the right.

Rinaldi I. Rada
Supervisory Patent Examiner
Group 3700